

BERNDL et al., Ser. No. 09/914,795

AMENDMENTS TO THE CLAIMS

1. (currently amended) A process for producing solid dosage forms having an accelerated release of active ingredient, which dosage forms are suitable for oral or rectal administration for humans and animals, wherein
  - a) 0.5 to 25% by weight of at least one active ingredient which is uncomplexed by cyclodextrin,
  - b) 0.5 to 60% by weight of at least one cyclodextrin selected from the group consisting of  $\alpha$ -,  $\beta$ -,  $\gamma$ - or  $\delta$ -cyclodextrins, the reaction products of cyclodextrins with alkylene oxide, alkyl halides, dialkyl sulfates, carbonyl chlorides, epihalohydrines, isocyanates or halogenated carboxylic acids, and polymer-modified cyclodextrins,
  - c) 15 to 98% by weight of at least one polymeric binder, selected from the group consisting of polyethylene glycol having a molecular weight above 4000, polyvinylpyrrolidone, and copolymers comprising N-vinylpyrrolidone and vinyl acetate, and
  - d) 0 to 50% by weight of conventional excipientsare mixed and plasticized at a temperature below 220°C 170°C without adding a solvent and the resulting plastic mixture is shaped to produce the dosage form.
2. (original) A process as claimed in claim 1, wherein the molar ratio between active ingredient and cyclodextrin is in the range from 0.1 to 4.0.
3. (previously amended) A process as claimed in claim 1, wherein the plastic mixture is shaped in a molding calendar to produce the dosage forms.
4. (original) A process as claimed in claim 3, wherein a molding calender with counterrotating molding rolls is used, with at least one of the molding rolls having on its surface depressions to receive and shape the plastic mixture.
5. (previously amended) A solid dosage form which is essentially free of aliphatic C<sub>2</sub>-C<sub>8</sub>-di- and -tricarboxylic acids and aromatic C<sub>6</sub>-C<sub>10</sub>-monocarboxylic acids, obtainable by a process as claimed in claim 1.
6. (original) A solid dosage form as claimed in claim 5, wherein at least 10% by weight of the active ingredient are present in the form of a cyclodextrin/active ingredient complex.

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7. (new) The solid dosage form of claim 5, said dosage form having release rate of active ingredient of at least 18% after 20 minutes, determined by the USP paddle method (0.1 M hydrochloric acid; pH 1.0; 150 rpm).
8. (new) The process of claim 1, wherein
  - a) 0.5 to 25% by weight of the at least one active ingredient;
  - b) 0.5 to 60% by weight of the at least one cyclodextrin,
  - c) 50 to 98% by weight of the at least one polymeric binder; and
  - d) 0 to 50% by weight of conventional excipientsare mixed and plasticized at a temperature below 170°C without adding a solvent and the resulting plastic mixture is shaped to produce the dosage form.